REMARKS / ARGUMENTS

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration claims 2-4, 6-9, and 11-14 remain unchanged, and claims 1, 5, and 10 have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a system for increasing the concentration of a gaseous or vapor phase in a sterilization or decontamination system. In known vaporized hydrogen peroxide (VHP) decontamination systems, VHP is continuously conveyed through a room or isolator. VHP exiting the room or isolator is directed to a destroyer to break down the VHP into water and oxygen. Such an arrangement allows the concentration of vaporized hydrogen peroxide within the room or isolator to be maintained at a desired concentration.

During a conditioning phase, a generator is used to generate VHP and to introduce the VHP into the circulation system. However, because the destroyer is disposed upstream of the generator in a closed loop system, the vaporized hydrogen peroxide is destroyed as it exits the room or isolator to be decontaminated even during a conditioning phase. As a result, the generator must continuously introduce new sterilant into the circulation system to replace sterilant that has been destroyed. Such a method of operation limits the rate at which the concentration of sterilant can be increased within the room or isolator during a conditioning phase.

The present invention provides a decontamination system that increases the rate at which the concentration of VHP can be increased within a room or isolator. The decontaminating system of the present invention includes a closed loop system for supplying vaporized hydrogen peroxide to a region. In one embodiment, the closed loop system includes a first flow path having a generator for generating vaporized hydrogen peroxide and a destroyer disposed therein. The destroyer is disposed upstream of the generator. In this respect, the destroyer and the generator are arranged "in series" along the same path. The VHP flows along the first flow path

through the destroyer and the generator. The closed loop system of the present invention also includes a bypass conduit that defines a second fluid flow path. The term "bypass" is defined as "a secondary pipe or other channel connected within a main passage, as for conducting a liquid or a gas around a fixture...." *The Random House Dictionary of the English Language* 287 (Stuart B. Flexner et al. eds., 2d ed., Random House 1987). As used herein, the term "bypass conduit" indicates a conduit for directing a fluid around the destroyer. In this regard, fluid flowing along the second fluid flow path bypasses the destroyer and flows through the generator.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a circulation system having a first fluid flow path and a second fluid flow path as presently set forth in the claims, or the advantages thereof.

In response to the Examiner's rejections, claims 1, 5, and 10 have been amended. Claim 1 has been amended to indicate that a controller is operable to cause said vaporized hydrogen peroxide generated by said generator to bypass the destroyer.

Claim 5 has been amended to indicate that said vaporized hydrogen peroxide generated by said generator bypasses said destroyer.

Claim 10 has been amended to indicate that the bypass conduit is for directing said vaporized sterilant through a second fluid path around the destroyer.

The Examiner has rejected claims 1-5 and 7-14 under 35 U.S.C. 103(a) as being unpatentable over PCT International Publication No. WO01/21223 A1 to Martin et al in view of U.S. Patent No. 5,906,794. The Martin et al. reference discloses an apparatus for sterilizing a sealable enclosure that includes a fluid circuit that has two "parallel branches." A "first parallel branch" contains means to deactivate a sterilant, i.e., the destroyer, and means to dehumidify the carrier gas. A "second parallel branch" contains means to heat the gas and means to supply a sterilant vapor or vapors, i.e., the generator, to the carrier gas. In other words, the generator and destroyer in the system disclosed in the Martin et al. reference are disposed in separate paths, i.e., are arranged "in parallel" and are not disposed "in series" along the same path.

The method of sterilizing disclosed by the Martin et al. references includes the following three steps that are executed in order: (1) reducing the relative humidity in the enclosure; (2) circulating the carrier gas containing the sterilant; and (3) removing the sterilant from the

enclosure. The destroyer is only operated during the third step and is used to completely remove sterilant from the carrier gas.

The Childers reference discloses a method and system for conducting a continuous operation, closed loop, flow-through vapor phase decontamination. The Childers reference discloses a system for vaporizing a liquid decontaminant and delivering the vaporized decontaminant into, through, and out of a sealable chamber through a closed loop conduit circuit. The system includes a first flow path and a second flow path. A first fluid flow line connects the first flow path to a dryer. A converter for destroying VHP and a generator for generating VHP are disposed along the first flow path. A second fluid flow line defines the second flow path around the dryer. A three-way valve is provided for varying the distribution of flow between the first flow path and the second flow path. In other words, the flow is split between the first flow path and the second flow path. In this manner, the degree of drying can be selected to achieve a desired humidity within the chamber. Thus, the Childers reference teaches a variable bypass around *a dryer*. The Childers reference does not teach, suggest, or show a bypass conduit that causes all sterilant to bypass a destroyer.

Neither the Martin et al. reference nor the Childers reference teaches, suggests, or shows a vapor decontamination system for decontaminating a defined region that includes a bypass conduit around a destroyer as required by claims 1, 5, and 10.

Neither reference teaches, suggests, or shows "a controller operable to cause said vaporized hydrogen peroxide generated by said generator to bypass said destroyer during a predetermined phase of operation," as required by claim 1. Neither reference teaches, suggests, or shows "a bypass conduit for causing substantially all fluid flow to flow through said closed loop system such that said vaporized hydrogen peroxide generated by said generator bypasses said destroyer," as required by claim 5. Further, neither reference teaches, suggests, or shows "a bypass conduit for directing said vaporized sterilant through said closed loop conduit system and through a second fluid path around said destroyer," as required by claim 10.

The Examiner does not explain the motivation for one skilled in the art to substitute the destroyer of Martin et al. reference for the dryer of the Childers reference. The dryer as disclosed in the Childers reference operates to vary the humidity within the chamber of the

Childers reference. In this regard, the three-way valve of the Childers reference is operable to direct *varying proportions of* fluid flow through the dryer. If the converter/sterilant destroyer of Martin et al. were substituted for the air dryer in Childers, the resulting device would not bypass the destroyer because some portion of carrier gas would pass through the destroyer. Further, neither reference teaches, suggests, or shows how such a varying or modulating control system would operate.

The Martin et al. reference explicitly teaches away from the process of continuous "cleansing and drying" taught by the Childers reference as likely to be wasteful (see Martin et al., page 2, line 13). In addition, the destroyer of the Martin et al. reference operates only after sterilization is completed. Thus, there is no suggestion in the Martin et al. reference nor the Childers reference to replace a dryer through which the carrier gas flow is modulated with a destroyer.

The Examiner states that it would be obvious to configure the converter/sterilant destroyer of Martin et al. in a controlled closed-circuit system with a bypass circuit, as the dryer in Childers is, because it would provide for *optimized recycling of the sterilant.* Applicant respectfully disagrees. Neither the Martin et al. reference nor the Childers reference teaches optimized recycling of the sterilant. Both references teach *total removal of the sterilant.*

To summarize, the present invention is directed to a system for increasing the concentration of a gaseous or vapor phase sterilant in a sterilization or decontamination system. The decontamination system of the present invention includes a closed loop system for supplying vaporized hydrogen peroxide to a region. In one embodiment, the closed loop system includes a first fluid path having a vaporized hydrogen peroxide generator and a destroyer disposed in series therein. The destroyer is disposed upstream of the generator. A bypass conduit defines a second fluid path. When flowing along the second fluid flow path, all fluid bypasses the destroyer and flows though the generator. All fluid either flows in the first fluid flow path or the second fluid path. The Applicants respectfully submit that the cited references do not teach, suggest, or show a circulation system having a bypass conduit around a destroyer as currently claimed.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teaches, suggests, or shows the Applicant's invention as defined by the present claims.

It view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8723US.

Respectfully submitted,

Date: **May 26, 2006**

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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: **May 26, 2006**

Laura K. Cahill